

REMARKS

By this Amendment, claims 20 and 33 are cancelled, and claims 19, 21-24 and 27 are amended. Claims 25-26, 28-32 and 34-37 remain in the application. Thus, claims 19, 21-32 and 34-37 are active in the application. Reexamination and reconsideration of the application are respectfully requested.

In item 3 on page 2 of the Office Action, claims 19-32 and 34 were rejected under 35 U.S.C. § 102(e) as being anticipated by Teeple, Jr. (U.S. 5,925,014, hereinafter "Teeple"). Further, in item 6 on page 3 of the Office Action, claim 33 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Teeple in view of Merki et al. (U.S. 5,002,055, hereinafter "Merki").

These rejections are respectfully traversed for the following reasons. Independent claim 19 has been amended to include the limitations of cancelled claims 20 and 33.

In particular, claim 19 recites an apparatus for supporting injection mixing work. The apparatus of claim 19 comprises an acquisition unit operable to acquire an injection prescription data including data specifying a plurality of injections which are prescribed to a patient.

The apparatus of claim 19 also comprises a memory unit operable to store corresponding relations between the data specifying the plurality of injections and pH-values data of the plurality of injections for deciding a mixing order of the plurality of injections before dosing the plurality of injections to a patient.

In addition, the apparatus of claim 19 comprises a decision unit operable to decide a proper mixing order of the plurality of injections included in the injection prescription data acquired by the acquisition unit based on the pH-values data for deciding a mixing order corresponding to the data specifying the plurality of injections stored in the memory unit.

Further, the apparatus of claim 19 comprises a display unit operable to display an indication representing the mixing order decided by the decision unit.

Claim 19 also defines that the decided mixing order displayed by the display unit is used to properly combine a plurality of the injections which are prescribed to the patient.

In items 10-14 on pages 3-5 of the Office Action, the Examiner disagreed with the Applicants' arguments presented in the Request for Reconsideration filed on March 15, 2006.

Specifically, in item 12 on page 5 of the final Office Action, the Examiner acknowledged that Merki discloses that pH-value data is used during an infusion to determine whether a prescribed medication can be mixed with another medication in accordance with their pH-values.

Although acknowledging that Merki does not disclose or suggest that pH-values data is used to determine a proper mixing order of a plurality of injections, the Examiner opined that it would have been obvious to modify the teachings of Merki and combine the modified teachings of Merki with the teachings of Teeple to result in the invention of cancelled claim 33.

Despite the Examiner's attempt to modify the teachings of Merki to result in the invention of cancelled claim 33, the Applicants respectfully submit that the Examiner has used impermissible hindsight to arrive at the present invention, and that the Examiner has not satisfied his burden of establishing a *prima facie* case of obviousness.

The Examiner is respectfully reminded that to establish a *prima facie* case of obviousness, the following three criteria must be met:

- (1) there must be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or combine the teachings of references,
- (2) there must be a reasonable expectation of success, and
- (3) the prior art references, when combining references, must teach or suggest all of the claim limitations. (see MPEP 2142)

Furthermore, MPEP 2142 clearly provides that "[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art" (emphasis added).

With regard to requirement (1), the Examiner contends that one skilled in the art would have modified Teeple and Merki in the manner that he proposes.

Nevertheless, with regard to requirements (2) and (3) for establishing a *prima facie* case of obviousness, the Examiner must demonstrate that the applied references

teach or suggest a reasonable expectation of success of combining the references, and that the applied references disclose or suggest all of the claim limitations. The Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for the following reasons.

Prior to a discussion of the teachings of the applied references, the Applicants note that, in items 12 and 13 on page 5 of the Office Action, the Examiner asserted that one cannot show nonobviousness by attacking references individually where the rejections are based on a combination of references. However, as demonstrated above, an obviousness rejection can only be established if a combination of references disclose or suggest all of the claim limitations. Accordingly, discussing references individually to demonstrate that they each fail to disclose or suggest all of the limitations of the claim does not amount to attacking references individually, because if the applied references each fail to disclose or suggest all of the claim limitations, the applied references cannot sustain an obviousness rejection.

The Examiner acknowledges that Teeple fails to disclose or suggest that a proper mixing order of a plurality of injections is determined based on pH-values data of the plurality of injections. It must be noted that Teeple fails to even contemplate using pH-values data in determining a mixing order of a plurality of injections. In an attempt to teach this feature, the Examiner applied Merki.

However, the Examiner's modification of Merki is unsupported by the disclosure of Merki, or by the disclosure of Teeple.

Merki discloses an apparatus for the biofeedback control of body functions by monitoring the body functions and administering medication automatically if these functions are outside predetermined limits. Merki is clearly directed to an apparatus for continuously monitoring biological body functions and automatically administering medications to a patient based on the measured body functions. In particular, Merki discloses that a pump for supplying medication is activated as a function of the measurements of body functions. Further, Merki discloses that medication doses are administered as a function of the measured values of biological body functions and a preselected threshold or target point. Merki discloses that a sensor continuously determines the effect of medication and selectively controls the operation of the pump to

meet the preselected threshold or target point of a patient's body functions. (see Column 1, lines 13-16 and 29-44).

Specifically, Merki discloses that sensors 1-3 monitor biological functions of a patient at preselected time intervals, and the measured values are compared with predetermined reference values stored in a memory or with reference values supplied by an administrator of the biofeedback control apparatus (see Column 2, line 60 to Column 3, line 3). Based on the measured values of the biological body functions of a patient, a microcomputer activates pumps to supply medications to achieve a desired therapy objective (see Column 3, lines 4-25). If the desired therapy objectives are not reached while infusing medications to a patient, Merki discloses that alarms 25, 28 notify an operator (see Column 3, lines 36-41).

Column 3, lines 52-63 of Merki disclose that a

pH-sensor 1 intraluminally measures the H^+ -ion activity. The measured data are stored and compared with the reference values stored in the microprocessor. For setting the therapy objective, e.g., raising the pH-value, microprocessor 12 activates the first pump for the administration with standard drugs, e.g., H₂-antagonist or ATP-ase inhibitors, either as a primed infusion, i.e., a bolus, followed by a continuous infusion or an intermittent infusion. The standard doses administered by the pump are increased or decreased stepwise by comparing the therapy objective with the patient's response.

Accordingly, Merki clearly discloses that measured pH-values data resulting from the infusion of a primary medication are stored and compared with the reference values that are stored in a microprocessor. Based on the measured pH-values data, Merki discloses that, during the infusion of a prescribed medication, another medication can be combined with the prescribed medication when the measured pH values are deemed to be unacceptable so as to achieve the desired therapy objective.

Therefore, similar to Teeple, Merki clearly does not disclose or suggest that pH-values data is used to determine a proper mixing order of a plurality of injections, because Merki clearly discloses that pH-values data is used to determine whether a medication that is being infused to a patient can be combined with another medication.

Consequently, according to the Examiner's interpretation of Teeple, the combination of Teeple and Merki can only be interpreted as disclosing or suggesting (1)

that a mixing order of injections is determined, and (2) that while injections are being administered to a patient, the pH-value of a patient's body can be measured, and based on the measured values, another medication can be combined with the injections that are already administered to the patient.

However, as described above, claim 19 recites that the memory unit of the apparatus is operable to store corresponding relations between the data specifying the plurality of injections and pH-values data of the plurality of injections for deciding a mixing order of the plurality of injections before dosing the plurality of injections to a patient. Claim 19 also recites that the decision unit is operable to decide a proper mixing order of the plurality of injections included in the injection prescription data acquired by the acquisition unit based on the pH-values data for deciding a mixing order corresponding to the data specifying the plurality of injections stored in the memory unit.

The Examiner even acknowledges that the Merki fails to disclose or suggest that pH-values data is used to determine a proper mixing order of a plurality of injections before the injections are dosed to a patient. Despite this acknowledgment, the Examiner only offers a conclusory assertion that it would have been obvious to one of ordinary skill in the art to modify the teachings of Merki to cure the deficiencies of Teeple and then arrive at the invention of claim 19.

However, as described above, to establish a *prima facie* case of obviousness, the applied references must teach or suggest all of the claim limitations, and the teaching or suggestion to make the claimed combination must be found in the applied references (see MPEP 2142).

The Examiner, however, has not demonstrated that the Teeple and Merki references disclose or suggest that a proper mixing order of a plurality of injections is determined based on pH-values data before dosing the plurality of injections to a patient. The Examiner has not demonstrated that the Teeple and Merki references disclose or suggest this feature of the present invention, because neither Teeple nor Merki disclose or suggest this feature of the present invention.

Teeple and Merki clearly fail to disclose or suggest:

(A) a memory unit operable to store corresponding relations between the data specifying the plurality of injections and pH-values data of the plurality of injections for

deciding a mixing order of the plurality of injections before dosing the plurality of injections to a patient, and

(B) a decision unit operable to decide a proper mixing order of the plurality of injections included in the injection prescription data acquired by the acquisition unit based on the pH-values data for deciding a mixing order corresponding to the data specifying the plurality of injections stored in the memory unit, as recited in claim 19.

The only suggestion of these features of claim 19 comes from the Examiner's conclusory assertion that it would have been obvious to one skilled in the art to modify Merki and then apply a modified Merki in order to cure the clear deficiencies of Teeple. However, the Examiner cannot satisfy his burden of establishing a *prima facie* case of obviousness unless the prior art suggest the desirability of the devised combination. MPEP 2143.01(III) clearly provides that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination" (emphasis in original). Accordingly, an attempted modification of a prior art reference or a combination of references that is unwarranted by the disclosure of the references is improper. Consequently, to establish a *prima facie* case of obviousness, the Examiner must make a showing that the desirability of combining and modifying two or more references was disclosed or suggested by the references. However, neither Teeple nor Merki suggest the desirability of combining or modifying their inventions in the manner envisioned by the Examiner.

Furthermore, the Examiner's modification of Merki changes the principle of operation of Merki. As clearly provided in MPEP 2143.02(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

As demonstrated above and as acknowledged by the Examiner, Merki discloses that, during the infusion of a prescribed medication, another medication can be combined with the prescribed medication when the measured pH values of a patient are deemed to be unacceptable so as to achieve the desired therapy objective. Accordingly, the principle operation of Merki is clearly directed to monitoring biological body functions

and automatically administering medications to a patient based on the measured body functions.

The Examiner's modification of Merki to cure the deficiencies of Teeple changes the principle operation of Merki. However, as clearly provided in MPEP 2143.02(VI), the teachings of a reference cannot be modified if the modification changes the principle operation of the reference.

Therefore, in addition to failing to disclose or suggest all of the limitations of claim 19, the Applicants respectfully submit that the Examiner's modification of Merki to cure the deficiencies of Teeple cannot be supported because the Examiner's modification of Merki changes the principle operation of Merki.

Accordingly, in addition to Teeple and Merki's failure to disclose or suggest features (A) and (B) of claim 19, the Examiner's hindsight-motivated modification of Merki is unwarranted and improper. An obviousness rejection cannot be based on the resort of the Examiner to various non-pertinent references and the combination of *bits and pieces of the references* in light of the Applicants' claimed invention. As described above, an obviousness rejection can only be sustained if the applied references teach or suggest all of the claim limitations, and the teaching or suggestion to make the claimed combination is found in the applied references (see MPEP 2142).

Clearly, for at least the foregoing reasons, neither Teeple nor Merki disclose or suggest features (A) and (B) of claim 19. Accordingly, requirement (3) of establishing *prima facie* obviousness of claim 19 has not been met.

Furthermore, as described above, to establish a case of *prima facie* obviousness, there must be a reasonable expectation of success for combining references, and the reasonable expectation of success must be found in the applied references.

However, neither Teeple nor Merki provide any basis from which to conclude that the modification of these references as contemplated by the Examiner would have a reasonable expectation of success. Accordingly, requirement (2) of establishing *prima facie* obviousness of claim 19 has also not been met.

Therefore, for at least the foregoing reasons, the Applicants respectfully submit that Teeple and Merki clearly fail to disclose or suggest each and every limitation of claim 19, and that the Examiner's proposed modification of Teeple and Merki is

unwarranted and improper, and fails to establish a *prima facie* case of obviousness of claim 19.

Consequently, the Applicants respectfully submit that claim 19 is clearly patentable over Teeple and Merki.

In item 8 on page 3 of the Office Action, claims 35-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Teeple, Jr. in view of Leissing et al. (U.S. 5,281,396, hereinafter "Leissing").

As demonstrated above, Teeple and Merki fail to disclose or suggest at least features (A) and (B) of claim 19. Similar to Teeple and Merki, Leissing also fails to disclose or suggest features (A) and (B).

Consequently, no obvious combination of Teeple, Merki and Leissing would result in the inventions of claim 19 since Teeple, Merki and Leissing, either individually or in combination, clearly fail to disclose or suggest each and every limitation of claim 19.

Therefore, it is submitted that the claim 19, as well as claims 21-32 and 34-37 which depend therefrom, are clearly allowable over the prior art as applied by the Examiner.

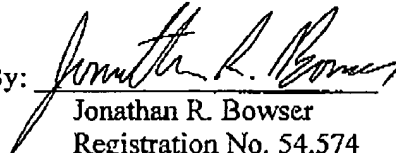
In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance. An early notice thereof is respectfully solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

A fee and a Petition for a two-month Extension of Time are filed herewith pursuant to 37 CFR § 1.136(a).

Respectfully submitted,

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